Complete Summary

GUIDELINE TITLE

Clinical policy: critical issues in the evaluation and management of adult patients presenting with suspected pulmonary embolism.

BIBLIOGRAPHIC SOURCE(S)

Clinical policy: critical issues in the evaluation and management of adult patients presenting with suspected pulmonary embolism. Ann Emerg Med 2003 Feb; 41(2):257-70. [145 references] PubMed

COMPLETE SUMMARY CONTENT

SCOPE

CATEGORIES

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Pulmonary embolism

GUIDELINE CATEGORY

Diagnosis Evaluation Management Treatment

CLINICAL SPECIALTY

Cardiology Critical Care Emergency Medicine Family Practice Internal Medicine Pulmonary Medicine Radiology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To address 2 major areas of interest and/or controversy:

- Diagnostic: utility of D-dimer, ventilation-perfusion scanning, and spiral computed tomography angiogram in the evaluation of pulmonary embolism (PE);
- Therapeutic: indications for fibrinolytic therapy

TARGET POPULATION

Adult patients presenting with signs or symptoms of pulmonary embolism (PE).

This guideline is not intended for pregnant patients or asymptomatic patients.

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

- 1. Estimation of pretest probability of pulmonary embolism (PE), using Wells, Wicki, or Kline criteria
- 2. D-dimer assay, using enzyme-linked immunosorbent assay (ELISA), latex agglutination, whole blood, turbidimetric, or immunofiltration assays
- 3. Ventilation-perfusion (V/Q) lung scan
- 4. Venous ultrasonography
- 5. Spiral computed tomography (CT) angiography

Management/Treatment

1. Indications for fibrinolytic therapy

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

An initial MEDLINE search for articles published from January 1995 through April 2001 was performed using the key words "pulmonary embolus" and yielded 5,004 hits. The search was therefore limited to clinical trials and clinical policies, which reduced the hits to 356. The abstracts from these articles were reviewed by subcommittee members who then met to select areas of critical importance on which to focus this policy. Pertinent practice guidelines reviewed in the development of this document included the 1996 American Heart Association "Management of Deep Vein Thrombosis and Pulmonary Embolism," the 1997 British Thoracic Society "Suspect Acute Pulmonary Embolism: A Practical Approach," the 1998 American College of Chest Physicians consensus statement "Opinions Regarding the Diagnosis and Management of Venous Thromboembolic Disease," the 1999 American Thoracic Society "The Diagnostic Approach to Acute Venous Thromboembolism," and the 2000 European Heart Society "Diagnosis and Management of Acute Pulmonary Embolism." Subcommittee members also supplied references with direct bearing on the policy by reviewing bibliographies of initially selected papers or from their own knowledge base.

NUMBER OF SOURCE DOCUMENTS

356

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

During the review process, all papers used in the formulation of this policy were classified by the subcommittee members into 3 classes based on design of study, with design 1 representing strongest evidence and design 3 representing weakest evidence for therapeutic, diagnostic, and prognostic clinical reports respectively. Reports were then graded on 6 dimensions thought to be most relevant to the development of a clinical guideline: blinded versus nonblinded outcome assessment, blinded or randomized allocation, direct or indirect outcome measures, biases (e.g., selection, detection, transfer), external validity (generalizability), and sufficient sample size. Articles received a final grade (I, II, III) based on a predetermined formula taking into account design and grade of study. Articles with fatal flaws were given an "X" grade and not used in the creation of this policy.

Literature Classification Schema*

Design/Class 1

Therapy[#]: Randomized, controlled trials or meta-analyses of randomized controlled trials

Diagnosis[&]: Prospective cohort using a criterion standard

Prognosis**: Population prospective cohort

Design/Class 2

Therapy#: Nonrandomized trial

Diagnosis[&]: Retrospective observational

Prognosis**: Retrospective cohort, case control

Design/Class 3

Therapy[#]: Case series, case report, other (e.g., consensus, review)

Diagnosis[&]: Case series, case report, other (e.g., consensus, review)

Prognosis**: Case series, case report, other (e.g., consensus, review)

*Some designs (e.g., surveys) will not fit this schema and should be assessed individually.

[#]Objective is to measure therapeutic efficacy comparing ≥2 interventions.

[&]Objective is to determine the sensitivity and specificity of diagnostic tests.

**Objective is to predict outcome including mortality and morbidity.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Clinical findings and strength of recommendations regarding patient management were made according to the following criteria:

Strength of Recommendations

Level A recommendations. Generally accepted principles for patient management that reflect a high degree of clinical certainty (i.e., based on "strength of evidence class I" or overwhelming evidence from "strength of evidence class II" studies that directly address all the issues).

Level B recommendations. Recommendations for patient management that may identify a particular strategy or range of management strategies that reflect moderate clinical certainty (i.e., based on "strength of evidence class II" studies that directly address the issue, decision analysis that directly addresses the issue, or strong consensus of "strength of evidence class III" studies).

Level C recommendations. Other strategies for patient management based on preliminary, inconclusive, or conflicting evidence or, in the absence of any published literature, based on panel consensus.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This policy is a product of the American College of Emergency Physicians (ACEP) clinical policy development process, including expert review, and is based on the existing literature; where literature was not available, consensus of emergency physicians was used. Expert review comments were received from individual emergency physicians; physicians from other specialties, such as cardiologists; and specialty societies, including members of the American College of Cardiology, American College of Chest Physicians, American College of Radiology, American Lung Association, and the Society of Thoracic Radiology. Their responses were used to further refine and enhance this policy.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the strength of evidence (Class I-III) and strength of recommendations (Level A-C) are repeated at the end of the Major Recommendations.

1. Can a negative D-dimer exclude pulmonary embolism (PE)?

Level A recommendations. None specified.

Level B recommendations. In patients with a low pretest probability of PE, use the following tests to exclude PE:

- 1. A negative quantitative D-dimer assay (turbidimetric or enzyme-linked immunosorbent assay [ELISA]).
- 2. A negative whole blood cell qualitative D-dimer assay in conjunction with a Wells´score of 2 or less.

Level C recommendations. In patients with a low pretest probability of PE, negative findings on a whole blood D-dimer assay (when not used with Wells' scoring system) or immunofiltration D-dimer assay can be used to exclude PE.

2. When can ventilation-perfusion (V/Q) scan alone or in combination with venous ultrasonography and/or D-dimer assay exclude PE?

Level A recommendations. In patients with a low-to-moderate pretest probability of PE, a normal perfusion scan reliably excludes clinically significant PE.

Level B recommendations. In patients with a low-to-moderate pretest probability of PE and a non-diagnostic V/Q scan, use 1 of the following tests instead of pulmonary arteriogram to exclude clinically significant PE:

- 1. A negative quantitative D-dimer assay (turbidimetric or ELISA).
- 2. A negative whole blood cell qualitative D-dimer assay in conjunction with a Wells´score of 4 or less.
- 3. A negative single bilateral venous ultrasonographic scan for low-probability patients.
- 4. A negative serial* bilateral venous ultrasonographic scan for moderate-probability patients (*serial venous ultrasonography refers to scheduling a patient for follow-up examination in the emergency department within 3 to 7 days or referring to a primary care physician for follow-up).

Level C recommendations. In patients with a low-to-moderate pretest probability of PE and a nondiagnostic V/Q scan, use a negative whole blood D-dimer assay (when not used with Wells´ scoring system) or immunofiltration D-dimer assay to exclude PE.

3. Can spiral computed tomography (CT) replace V/Q scanning in the diagnostic evaluation of PE?

Level A recommendations. None specified.

Level B recommendations. Thin collimation spiral CT scan of the thorax with 1- to 2-mm image reconstruction may be used as an alternative to V/Q scan during the diagnostic evaluation of patients with suspected PE.

Level C recommendations. Spiral CT scan of the thorax with delayed CT venography may be used for increased detection of patients with significant thromboembolic disease.

4. What are the indications for fibrinolytic therapy in patients with PE?

Level A recommendations. None specified.

Level B recommendations. Consider fibrinolytic therapy in hemodynamically unstable patients with confirmed PE.

Level C recommendations. Consider fibrinolytic therapy in:

- 1. Hemodynamically stable patients with confirmed PE and right ventricular (RV) dysfunction on echocardiography.
- 2. Unstable patients with high clinical index of suspicion (especially if RV dysfunction can be demonstrated on bedside echocardiography).

Definitions:

Strength of Evidence

Literature Classification Schema*

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Strength of Recommendations

Level A recommendations. Generally accepted principles for patient management that reflect a high degree of clinical certainty (i.e., based on "strength of evidence class I" or overwhelming evidence from "strength of evidence class II" studies that directly address all the issues).

Level B recommendations. Recommendations for patient management that may identify a particular strategy or range of management strategies that reflect moderate clinical certainty (i.e., based on "strength of evidence class II" studies that directly address the issue, decision analysis that directly addresses the issue, or strong consensus of "strength of evidence class III" studies).

Level C recommendations. Other strategies for patient management based on preliminary, inconclusive, or conflicting evidence or, in the absence of any published literature, based on panel consensus.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVI DENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Accurate diagnosis of pulmonary embolism (PE)
- Appropriate management of patients with PE

POTENTI AL HARMS

Increased risk of intracranial hemorrhage and mortality from fibrinolytic therapy

^{*}Some designs (e.g., surveys) will not fit this schema and should be assessed individually.

[#]Objective is to measure therapeutic efficacy comparing >2 interventions.

[&]Objective is to determine the sensitivity and specificity of diagnostic tests.

^{**}Objective is to predict outcome including mortality and morbidity.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Recommendations offered in this policy are not intended to represent the only diagnostic and management options that the emergency physician should consider. The American College of Emergency Physicians (ACEP) clearly recognizes the importance of the individual clinician's judgment. Rather, they define for the clinician those strategies for which medical literature exists to provide strong support for their utility in answering the crucial questions addressed in this policy.
- This policy is not intended to be a complete manual on the initial evaluation and management of patients with suspected pulmonary embolism (PE) but rather a focused look at critical issues that have particular relevance to the practice of emergency medicine.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Clinical policy: critical issues in the evaluation and management of adult patients presenting with suspected pulmonary embolism. Ann Emerg Med 2003 Feb; 41(2):257-70. [145 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Feb

GUI DELI NE DEVELOPER(S)

American College of Emergency Physicians - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Emergency Physicians

GUIDELINE COMMITTEE

American College of Emergency Physicians (ACEP) Clinical Policies Subcommittee on Suspected Pulmonary Embolism

ACEP Clinical Policies Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUI DELI NE STATUS

This is the current release of the guideline.

This release of the guideline represents a revision of a 1995 American College of Emergency Physicians chest pain policy (American College of Emergency Physicians. Clinical policy for the initial approach to adults presenting with a chief complaint of chest pain, with no history of trauma. Ann Emerg Med 1995; 25: 274-299) as it relates to the initial approach to patients with signs and symptoms of pulmonary embolism.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the <u>American College of Emergency Physicians Web site</u>.

Print copies: Available from the American College of Emergency Physicians, ACEP Customer Service Department, P.O. Box 619911, Dallas, TX 75261-9911, or call toll free (800) 798-1822, touch 6.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on June 5, 2003. The information was verified by the guideline developer on July 18, 2003.

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